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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,208	02/08/2002	Patrick Bernardelli	A0000135-01-CFP	8057

7590

11/26/2003

Claude F Purchase Jr
Warner Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER

HABTE, KAHSA Y

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,208

Applicant(s)

BERNARDELLI, PATRICK

Examiner

Kahsay Habte, Ph. D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 18-37 are pending.

Response to Amendment

2. Applicant's amendment filed 11/13/03 in response to the previous Office Action (Paper No. 5) is acknowledged. Rejections of claims 1-17 under 35 U.S.C. § 112, first and second paragraph (Paper No. 5, paragraphs 2 and 4a-4b) have been obviated. The enablement rejection in item 3 has been maintained.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the oxidation of diazepam (see example 2, compound 1), does not reasonably provide enablement for the oxidation of any organic compound having at least one nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon double bond. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There has been recited a process for the oxidation of an organic compound having at least one nitrogen atom, sulfur atom, hydroxy group, but the specification is not enabled for such a scope.

Applicants claim the oxidation of any organic compounds having at least one nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon double bond, but it is not plausible to oxidize all organic compounds having at least one nitrogen atom, sulfur atom, hydroxy or carbon-carbon double bond with a reaction medium comprising a metalloporphyrin of formula I and an oxidizing agent in an inert aromatic solvent. It is required that applicants claim to what actually are entitled to. It requires undue experimentation to find out, which organic compounds/groups. According to the instant invention, any compound with at least one nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon double bond that covers a wide variety of organic compounds are encompassed by the claim. For example, the following compounds/groups are covered by the claim: azepine, trimethylamine, azo compounds, pyrimidines, pyrazines, piperazines, pyridazines, pyrroles, diazoles, peptides, nucleic acids, alcohols, alkanes, amines, aldehydes, olefins, ketones, oximes, sulfides, thiols, thiophenes, thienes, etc. Applicant's specification does not enable for such scope of compounds/groups. Since applicants did not provide enough support for their invention, the enablement rejection is proper. It is recommended that applicants claim the invention, for which they have support (i.e. oxidation of diazepam).

Response to arguments

Applicants' arguments filed 11/13/2003 have been fully considered but they are not persuasive.

Applicants argue that the specification on pages 2-3 discloses characteristics of the organic compounds. The examiner disagrees with applicants. The specification in pages 2-3 does not provide enough guidance for one skilled in the art to carry out the invention. The specification on page 2 disclose: "compounds containing heteroatoms, such as nitrogen or sulfur, can be efficiently oxidized...", but this disclosure would not overcome the enablement rejection. Applicant's amendment partially overcome the enablement rejection by reciting specific metalloporphyrin that is represented by formula 1, but failed to narrow down the invention to the oxidation of diazepam (EXAMPLE 1). For example on page 2 of the specification (line 26), "Preferably, compounds containing heteroatoms, such as nitrogen or sulfur, can be efficiently oxidized through the process of the invention..." does not enable one skilled in the art to carry out the invention. There are million and million chemical structures that contain at least one sulfur, nitrogen, hydroxy, or carbon-carbon double bond. It takes undue experimentation to determine which organic compounds that contain nitrogen or sulfur are oxidized and which are not.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 18 and claims dependent thereon are rejected because the phrase “organic compound having at least one nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon double bond” is indefinite. What are covered and what are not? How can one tell which organic compounds are covered and which are not?

Response to arguments

Applicants’ arguments filed 11/13/2003 have been fully considered but they are not persuasive.

Applicants have deleted claim 1 and replaced it with new claim 18, but the amendment would not overcome the rejection. The claim as amended “organic compound having at least one nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon double bond” is still indefinite. What is the nature of the organic compounds with at least one nitrogen? Are they aliphatic? Carbocyclic? Heterocyclic? Or all? The specification does not provide any guidance so that one skilled in the art recognizes what organic compounds are covered and what are not.

b. In claim 18, the phrase “at least one nitrogen atom, sulfur atom, hydroxy group, or carbon-carbon double bond” is indefinite. What is the upper limit? Is a compound with 20 nitrogens oxidized? What about an organic compound with 100 nitrogens? 200 sulfur atoms?

c. Claim 19 recites the limitation "further comprises a polyhalogenated aliphatic solvent" in line 2. There is insufficient antecedent basis for this limitation in the claim. There is no mention of "polyhalogenated aliphatic solvent" back in claim 18. Claim 18 recites "an inert aromatic solvent" that is narrower in scope compared to original claim 1. Original claim 1 recites the broader term "inert aprotic solvent selected from a polyhalogenated aliphatic or aromatic solvent", but new claim 18 does not recite said broader term.


Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Kahsay Habte, Ph. D.
Examiner
Art Unit 1624


Mukund J. Shah
Supervisory Patent Examiner
Art Unit 1624

KH
November 21, 2003